ADVANCED BIO-SURFACES, INC.

K073233 (pg 1/3)

510(k) Summary

Advanced Bio-Surfaces, Inc.

OrthoGlide® Lateral Knee Implant

JAN 28 2008

510(k) Notification _____

MANUFACTURER INFORMATION

Name & Address: Advanced Bio-Surfaces, Inc.
5909 Baker Road, Suite 550
Minnetonka, MN 55345 USA

Summary Prepared: November 12, 2007

Contact: Albert Schafer
Manager, Q.A. / Regulatory Affairs
952-912-5400 phone
952-912-5410 fax

DEVICE INFORMATION

Trade Name: OrthoGlide® Lateral Knee Implant

Classification Name: 21CFR 888.3590 – Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

Product Code: HSH

Common / Usual Name: Hemi- knee prosthesis

Substantial equivalence: The ABS OrthoGlide Lateral Knee Implant is substantially equivalent to FDA approved predicate devices with regard to indications for use, materials, technological characteristics and surgical techniques. These predicate devices are: Sulzer Orthopedics, Inc. Unicondylar Interpositional Spacer (K003269)

ITI, Knee Interpositional Mini-Repair system (KIMRS) (K033242)

5909 Baker Road, Suite 550 • Minnetonka, MN 55345 • Phone: (952) 912-5400 • Fax: (952) 912-5410

ABS OrthoGlide® Medial Knee Implant (K053094)

Device Description: The OrthoGlide Lateral Knee Implant is placed in the lateral compartment of the knee between the tibial plateau and femoral condyle by means of **minimally invasive surgery.** The instruments are intended to aid in the surgical preparation of the implant site and implant placement. The OrthoGlide is made of a Cobalt-Chrome-Molybdenum Alloy. Device geometry and ligament tension combine to keep the implant in place. The implant covers the lateral tibial plateau. The device is designed to improve the alignment of the knee, returning the joint to a less valgus position. Realignment of the knee distributes the weight-bearing forces across the joint and helps restore the normal relationships of the articular surfaces and the surrounding capsular, ligamentous and muscular structures.

The device is designed to help relieve pain by providing an articulating surface with a low coefficient of friction and high durability. Device geometry improves knee alignment and joint spacing. The device surface is smooth and when wet, is intended to mimic the lubricious surface previously provided by the articular cartilage.

Intended Use: The OrthoGlide Lateral Knee Implant is intended for use in the osteoarthritic knee, where a substantial amount of cartilage has been lost as a result of the disease. The device is indicated for uncemented use in the treatment of moderate degeneration of the Lateral compartment of the knee (grade II-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the medial and patellofemoral compartments in patients with osteoarthritis.

Substantial Equivalence: The ABS OrthoGlide Lateral Knee Implant is substantially equivalent to FDA approved predicate devices with regard to indications for use, materials, technological characteristics and surgical techniques. OrthoGlide offers no additional risks to the patient and the materials and manufacturing methods add no new or additional safety concerns. The OrthoGlide as well as the predicates are submitted without clinical information. The substantially equivalent predicate devices are:

Sulzer Orthopedics, Inc. Unicondylar Interpositional Spacer (K003269)

ITI, Knee Interpositional Mini-Repair system (KIMRS) (K033242)

ABS OrthoGlide Medial Knee Implant (K053094)

Testing: The OrthoGlide Implant has been developed, verified and validated in compliance with a comprehensive design process. The corresponding Bench Testing has been accomplished according to a Master Test Plan for the device. The test plan shows the required test, the source of the requirement, the protocol and the report. If the method is from a standard, the voluntary standard is referenced. The bench testing has demonstrated the physical attributes and durability of the OrthoGlide by tensile elongation, load deflection, cyclic fatigue resistance, material consistency and stability and processing control.

Cadaver testing has verified the surgical technique and instruments. Cadaver evaluations have also verified the desired physiological effects of stability and range of motion preservation.

The OrthoGlide also demonstrated that it meets internationally recognized standards for biocompatibility (ISO 10993), sterility (EN550), and conformance to material specifications. Clinical testing was not used to determine substantial equivalence.

Summary: Based on the evidence of substantial equivalence the OrthoGlide is considered to be safe and effective and will perform as well or better than the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2008

Advanced Bio-Surfaces, Inc.
% Mr. Albert Schafer
Manager, Q.A./Regulatory Affairs
5909 Baker Road, Suite 550
Minnetonka, MN 55345

Re: K073233
Trade/Device Name: OrthoGlide® Lateral Knee Implant
Regulation Number: 21 CFR 888.3590
Regulation Name: Knee joint tibial (hemi-knee) metallic resurfacing uncemented prothesis
Regulatory Class: II
Product Code: HSH
Dated: December 30, 2007
Received: January 29, 2008

Dear Mr. Schafer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073233 (pg 1/1)

Indications for Use

510(k) Number (if known):

Device Name: OrthoGlide® Lateral Knee Implant

Indications for Use:

The OrthoGlide Lateral Knee Implant is intended for use in the osteoarthritic knee, where substantial amounts of cartilage have been lost as a result of the disease. The device is indicated for uncemented use in the treatment of moderate degeneration of the lateral compartment of the knee (grade II-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the medial and patellofemoral compartments in patients with osteoarthritis.

Prescription Use _Yes_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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